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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/721,479 | 11/22/2000 | Doris Coit | PP01617.002 | 2173 |

7590 08/27/2002

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EXAMINER

BROWN, STACY S

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 08/27/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/721,479

Applicant(s)

COIT ET AL.

Examiner

Stacy S Brown

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-42 is/are pending in the application.
- 4a) Of the above claim(s) 20-31 and 33-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-19 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 June 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment mailed June 18, 2002 is acknowledged and entered. Claims 1, 2 and 4-42 are pending. Claims 20-31 and 33-42 are withdrawn from consideration. Claims 1, 2, 4-19 and 32 are examined.
2. This application contains claims 20-31 drawn to an invention nonelected with traverse in Paper No. 20. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

3. As requested, PTO-1449 (Paper No. 6) is attached to this Office Action.

Response to Amendment

4. The objection to the specification is withdrawn in view of Applicant's amendment. The rejection of claims 13-15 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendment. The rejection of claims 1-3 under 35 U.S.C. 102(b) as anticipated by Bartenschlager *et al.* (*Journal of Virology* (1993) 67:3835-3844) is withdrawn in view of Applicant's amendment.

Response to Arguments

5. Applicant's arguments have been fully considered but fail to persuade. Claims 1-19 and 32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bartenschlager *et al.* (*Journal of Virology* (1993) 67:3835-3844) in view of Houghton *et al.* (EP 0693687) and

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Miyamura *et al.* (U.S. Patent 5,372,928) for reasons of record, and in view of the following arguments.

The amended claims are drawn to an isolated mutant NS HCV polypeptide having a C-terminal portion of NS3 and a deletion of more than 60 amino acids from the N-terminus of NS3. The deletion functionally disrupts the catalytic domain of NS3. The deletion can be at least 200 amino acids.

Applicant mainly argues that:

- *Bartenschlager fails to teach or suggest a polypeptide having a deletion of more than 60 amino acids from the N-terminus.*
 - In response, the Office acknowledges that Bartenschlager fails to teach a deletion of more than 60 amino acids from the N-terminus of HCV NS3. However, Bartenschlager demonstrates (Figure 5) that a deletion of 60 amino acids rendered the protease non-functional. Bartenschlager does not appear to have deleted more than 60 amino acids because he found the amino acid (or range of amino acids) at which the protease would be rendered non-functional, albeit the reasons for the lack of protease activity are not clear (page 3840, col. 2).
 - According to Applicant's specification, the catalytic domain of NS3 is defined as the protease active site region, see page 11, lines 19-20. Bartenschlager's deletion results in a non-functional protease (functionally disrupting the catalytic domain), see abstract. Lacking evidence to the contrary, an amino acid deletion of more than 60 amino acids resulting in a non-functional protease is expected in view of because *the claimed polypeptide contains the deletion of Bartenschlager.*

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Applicant is invited to point out the special properties of a polypeptide having a deletion of more than 60 amino acids that Bartenschlager's polypeptide lacks.

- *There is no motivation to use Bartenschlager's deletion mutant in a pharmaceutical composition. Bartenschlager (page 3843) does not refer to the preparation of immunogenic compounds comprising the deletion mutant polypeptide, rather developing drugs that target the protease.*

- In response, the Office agrees that Bartenschlager fails to suggest the use of the deletion mutant in a pharmaceutical composition. However, the specification says that amino acids 1207-1278 of NS3 (page 3) represent an immunodominant region for CD4+ T cells. Given this knowledge, one of ordinary skill in the art would have been motivated to use Bartenschlager's mutant in an immunogenic composition, such as Miyamura or Houghton. Houghton uses a similar deletion mutant having NS3 amino acids 1192-1457, which includes the immunodominant region. One would have had a reasonable expectation of success that Bartenschlager's mutant would be immunogenic because it contains the immunodominant region referred to in the specification.

Conclusion

6. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

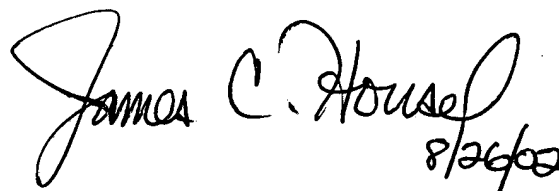
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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stacy S. Brown
August 20, 2002



JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600